

**REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 1-11, 21-23 and 25 are in the case.

**I. PRIORITY**

The Action asserts that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120. This point was discussed with the Examiner (Dr. Priebe) and with Special Programs Examiner, William Dixon, on January 10, 2006. Mr. Dixon advised that the claim for priority presented with the application upon filing was correct but required amendment to refer to the December 23, 2003 filing date accorded to Application Serial No. 10/433,681 as a result of the later submission of the executed Declaration on December 23, 2003. In view of this, no petition is believed to be required. Withdrawal of the objection to the priority claim is accordingly respectfully requested.

**II. CLAIM OBJECTIONS**

Claims 5, 21 and 29 have been objected to in view of the informalities mentioned on page 4 of the Action. In response, claim 5 has been amended to incorporate the language "the group consisting of" and "encodes a protein" after "gene". Claim 21 has been amended as suggested by the Examiner. Claim 29 has been cancelled without prejudice. Withdrawal of the claim objections is now respectfully requested.

**III. THE 35 U.S.C. §112, FIRST PARAGRAPH, REJECTION**

Claims 6, 16 and 22 stand rejected under 35 U.S.C. §112, first paragraph, on alleged lack of enablement grounds. That rejection is respectfully traversed.

The Examiner asserts that while the specification is enabling for insertion of a therapeutic or suicide gene into the adenoviral major late transcription unit after the L5 (fibre) gene (claims 6, 16 and 22) or into adenoviral E3 under control of the E3 promoter (claim 22), the specification allegedly does not provide enablement for any other site of insertion of the therapeutic or suicide gene. In response, and without conceding to the merit of this rejection, claim 1 has been amended to specify that the therapeutic gene is positioned at a location selected from a location between the adenovirus fibre gene and the adenovirus E4 region in the major late transcription unit of the viral's construct at a location under control of the E3 promoter. The claims as now amended are supported by an enabling disclosure. Withdrawal of the lack of enablement rejection is respectfully requested.

#### **IV. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 1-31 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for the reasons detailed on page 6 and 7 of the Action. That rejection is respectfully traversed.

The claims have been amended to deal with the points raised by the Examiner. In particular, amended claim 1 now recites that the construct comprises a **wild type** adenovirus sequence having human or animal transcription factor binding sites operatively positioned together with the adenovirus E1A open reading frame. The antecedent basis requirement has now been satisfied.

Claim 24 has been rejected as allegedly not making sense. In response, claims 12-19, 20, 24, 26-29 and 31 have been cancelled, and the dependencies of claims 21 and the remaining later claims have been amended so as to be dependent on claim 1. Withdrawal of the 35 U.S.C. §112, second paragraph, rejection is now respectfully requested.

#### **V. THE ANTICIPATION REJECTION**

Claims 1, 3, 4, 7, 9-15, 17-22 and 24-30 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 00/56909 to Iggo et al. In response, and without conceding to the merit of this rejection, claim 1 has been amended to specify state that the construct has wild type transcription factor binding sites for the E2 and E3 open reading frames. Iggo relates to tumor specific transcription factor binding site control of one or more early viral protein gene open reading frames so as to promote expression of these open reading frames encoding for proteins mechanistically directly involved in viral construct nucleic acid replication, selected from viral polymerase, primase, nuclease, helicase, ligase, DNA terminal protein and DNA binding protein. Reference is also made to adenovirus constructs having non-wild type E2 and E3 promoters.

In contrast, the present invention focuses on the surprising discovery that viruses that have wild type E2 promoter controlling the E2 open reading frame proteins are selective and yet active in semi-permissive cell lines. In light of this, it is believed that Iggo does not anticipate the invention as now claimed. Withdrawal of the outstanding anticipation rejection is respectfully requested.

**VI. THE 35 U.S.C. §102(f) and (g) REJECTION**

With the amendments made in the present response, it is believed that no overlap exist with the claims of U.S. Patent 6,544,507 and U.S. Application No. 10/376,630. Withdrawal of the outstanding rejection under 35 U.S.C. §102(f) and (g) is accordingly respectfully requested.

**VII. DOUBLE PATENTING**

The Action indicates that should claim 3 be found allowable, claim 13 will be objected to as being a substantial duplicate thereof. In response, and without conceding to the merit of this rejection, claim 13 has been cancelled without prejudice.

Claims 1, 3, 4, 7, 9-15, 17-22 and 24-30 stand rejected on obviousness-type double patenting grounds as allegedly unpatentable over claims 1-23 of U.S. Patent 6,544,507. In response, it is believed that the invention as now claimed is not rendered obvious by the claims of the '507 U.S. Patent.

Claims 1, 3, 4, 7, 9-15, 17-22 and 24-30 are provisionally rejected on obviousness-type double patenting grounds as allegedly unpatentable over claims 1, 3-10, 14-21, 23, 26-29 and 32-37 of co-pending Application Serial No. 10/376,630. In addition, claims 1-30 stand provisionally rejected on obviousness-type double patenting grounds as allegedly unpatentable over claims 1-35 of co-pending Application Serial No. 10/433,681. In response, it is requested that these two provisional obviousness-type double patenting rejections be placed in abeyance until prosecution has been completed with respect to the other two applications, at which time a determination can

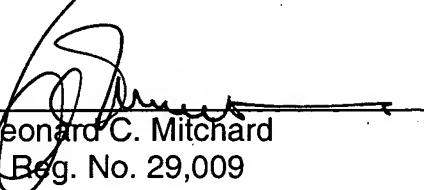
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be made as to whether or not obviousness-type double patenting exists between the various sets of claims. Such action is respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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